



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL - 2 1999

6542 '99 JUL -6 P1:41

Ronald L. Girmus, PhD.
4390 West Red Mountain Road
Bisbee, Arizona 85603

Dear Dr. Girmus:

Thank you for your recent inquiry to Senator John McCain, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation. Senator McCain has asked us to respond directly to you.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

98N 1038

ANS4

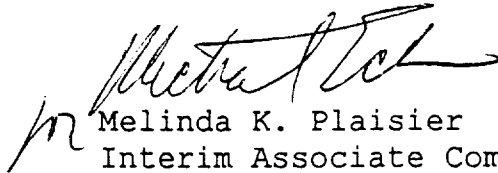
Page 2 - Ronald L. Girmus, PhD.

We have forwarded your correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

In regard to irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,


Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: The Honorable John McCain
United States Senate
Washington, D.C. 20510-0303

Dockets Management Branch ✓
(98N-1038)

JOHN McCAIN
ARIZONA

CHAIRMAN, COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION
COMMITTEE ON ARMED SERVICES
COMMITTEE ON INDIAN AFFAIRS

United States Senate

May 26, 1999

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Ms. Diane Thompson
Legislative Affairs
Food and Drug Administration
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857-0001

Dear Diane:

I have enclosed inquiries which I have received from several of my constituents from Arizona.

I would greatly appreciate it if you would review this material within existing rules, regulations and ethical guidelines. Please send a prompt response addressing this issue to each of these constituents, and provide me with copies of the responses for my records.

PLEASE SEND THE COPY TO THE ATTENTION OF: Brian Roth in my Washington office, 241 Russell Senate Office Building, Washington, D.C. 20510. Thank you very much for your kind assistance and cooperation.

Sincerely,



John McCain
United States Senator

JM/ina
Enclosures

No 99-3758

Ronald L. Girmus, PhD. 4390 West Red Mountain Road Bisbee, Arizona 85603

May 7, 1999

Senator John McCain
241 Russel Senate Office Building
Washington, DC 20510

Dear Senator McCain:

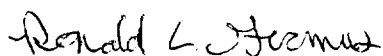
Enclosed is a letter submitted to the FDA-regarding labeling requirements for irradiated foods which are currently under review.

Food irradiation causes molecular changes in food. It creates chemical substances within the irradiated food called "radiolytic products." Some radiolytic products, such as formaldehyde, benzene, formic acid, and quinones are harmful to human health. Benzene, for example, is a carcinogen. In one experiment, seven times more benzene was found in cooked, irradiated beef than in cooked, non-irradiated beef. Some of the radiolytic products unique to the irradiation process are completely new chemicals that have not even been identified, let alone tested for toxicity.

In addition, irradiation destroys essential vitamins and minerals, inducing vitamin A, thiamine, B2, B3, B6, B12, folic acid, C, E, and K. Amino acid and essential polyunsaturated fatty acid content may also be affected. A 20 to 80 percent loss of any of these is not uncommon.

Since the use of irradiation in food production, processing, and handling causes real and measurable changes in the food that is treated, consumers must have the ability to identify which foods have been treated with irradiation and they must have ready and identifiable access to other, non-irradiated foods. I urge you to support the maintenance of the FDA's current labeling requirements of all irradiated foods and all foods containing irradiated ingredients.

Sincerely,



Ronald L. Girmus, Ph.D.

Ronald L. Girmus, PhD. 4390 West Red Mountain Road Bisbee, Arizona 85603

May 7, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-1038, Irradiation in the Production, Processing, and Handling of Food

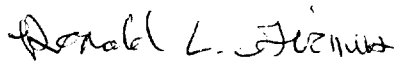
To whom it may concern:

I support the recommendation by the Center for Science in the Public Interest regarding labeling of irradiated foods: "any foods, or any foods containing ingredients that have been treated by irradiation, should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed on close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale."

Like other labels, irradiation labels are required to be truthful and not misleading. The terms "treated with irradiation" or "treated with irradiation" should be retained. Any phrase involving the word "pasteurization" is misleading because pasteurization is an entirely different process of rapid heating and cooling.

As a scientist with a PhD. in human physiology, I am especially concerned with the potential public health effects of this technology which is to be used on the human food supply without the benefit of long-term human feeding studies. Because of the newness of irradiation in food processing and the need to assist the long term health effects of the widespread ingestion of irradiated food, I believe that the FDA's labeling requirements should not be allowed to expire.

Sincerely,



Ronald L. Girmus, Ph.D.

cc: Representative Jim Kolbe
Senator Jon Kyl
Senator John McCain